Long-term outcome and reintervention after endovascular abdominal aortic aneurysm repair using the Zenith stent graft

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Objective: **To assess the long-term performance of the bifurcated Zenith stent graft.**

Methods: **A total of 325 patients (300 men and 25 women) underwent elective endovascular abdominal aortic aneurysm repair with bifurcated Zenith stent grafts between October 1998 and December 2005. Follow-up included routine contrast-enhanced computed tomography and multiview abdominal radiographs at 1, 6, and 12 months and yearly thereafter. Data on late-occurring (>30 days after stent-graft implantation) complications and interventions were collected prospectively.**

Results: **Of the original 325 patients, 92 have since died, resulting in a mean follow-up of 2.3 years (range, 1 month to 7.0 years). Nine (2.8%) of 325 patients required reintervention to treat or prevent endoleak (type I or III) or graft occlusion at an average of 1.4 years after stent-graft placement (range, 40 days to 4.0 years). Three (0.9%) of these patients died from causes related to malfunction of the stent graft: one each from aneurysm rupture, stent-graft infection, and infection of a femoral-femoral bypass graft placed after limb occlusion. Nineteen additional patients (5.8%) required treatment for type II endoleak, for a total reintervention rate of 8.6%.**

Conclusions: **Late failures of Zenith stent-graft attachment, structure, or function are rare. In the absence of known endoleak, routine follow-up imaging plays a limited role in the identification and prevention of impending failure. (J Vasc Surg 2007;45:461-6.)**

Endovascular abdominal aortic aneurysm (AAA) repair depends on the presence of an intraluminal stent graft to exclude the aneurysm from arterial flow and pressure, thereby preventing aneurysm dilatation and rupture while maintaining flow to distal organs. Although the ultimate goal may be the prevention of aneurysm rupture, endovascular aneurysm repair can also be considered a failure when blood flows outside the confines of the stent graft (endoleak), the graft occludes, or additional interventions are necessary.

Stent grafts differ in their ability to traverse the iliac arteries and gain hemostatic implantation above and below the aneurysm. They differ even more in their ability to withstand the cyclical stresses and strains imposed by hemodynamic forces.[1-3] Stent-graft materials, shapes, and attachment mechanisms vary widely, as do the long-term results of endovascular aneurysm repair. Large prospective studies[4-6] and registries[1] have failed to produce the kind of device-specific data on the long-term functional outcome of endovascular aneurysm repair that are needed for informed decisions on patient selection, device selection, and follow-up.

Predicate designs of the Zenith stent graft (Cook Inc, Bloomington, Ind) were first implanted in 1994. We began using the current device in 1998, and widespread use in the United States followed Food and Drug Administration approval in 2003. Long-term results have yet to be reported. The initial industry-sponsored study required only 2 years of follow-up.[7] Although the study period has since been extended, the results have not been vetted, analyzed, or published.

This single-center report focuses on the function of the standard Zenith stent graft and the interventions necessary to maintain stent-graft function. We have also attempted to identify the timing, causes, and effects of failing stent-graft function as a basis for future patient selection and follow-up.

METHODS

A total of 325 patients underwent elective endovascular AAA repair by using bifurcated Zenith stent grafts between October 1998 and December 2005 at the University of California–San Francisco Medical Center. Data on late-occurring (>30 days after stent-graft implantation) complications and interventions were collected prospectively. Subjects were excluded from the analysis if the operation was urgent or emergent or involved the implantation of uni-iliac, fenestrated, or multibranched devices. Follow-up included routine contrast-enhanced computed tomography (CT) and multiview abdominal radiographs at 1, 6, and 12 months and yearly thereafter. Exhaustive efforts to identify all causes of death included interviewing the pa-

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Competition of interest: Dr Chuter has licensed patents to Cook, Inc, the manufacturer of the Zenith stent graft.

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tient's relatives, reviewing pertinent hospital records, and obtaining all available death certificates.

Patient demographic information, including age, sex, aneurysm size, medical comorbidities, and creatinine levels, were collected prospectively. Before approval of the Zenith stent graft in 2003, all patients were enrolled in a single-center investigational device exemption protocol, for which one of the selection criteria specified high-risk status. All these high-risk patients had serious comorbid conditions. Data on medical comorbidities included the presence of diabetes mellitus, chronic obstructive pulmonary disease, and cardiac disease. Cardiac disease included any history of myocardial infarction, congestive heart failure, ischemic heart disease, or atrial fibrillation.

Failure of stent-graft function included failure to exclude the aneurysm from direct aortic flow (endoleak type I or III) and failure to convey blood to the iliac arteries (graft occlusion). Impending failure of stent-graft function included component separation (without endoleak) and kinking of the stent graft (without thrombosis). In terms of clinical outcome, the distinction is unimportant; they all resulted in reintervention. Those occurring more than 30 days after stent-graft implantation are combined here as cases of late failure, although they might equally well be termed late reintervention.

Cases of type II endoleak, and reintervention for type II endoleak, were analyzed separately in the absence of its contribution as a primary failure mode. Invasive treatment for a type II endoleak consisted of coil embolization of either the inferior mesenteric artery or the lumbar arteries. The selection criteria for endovascular AAA repair, methods of device insertion, and follow-up protocol did not change during the course of the study. However, the indications for treatment of a type II endoleak did change. Initially, the presence of any type II endoleak on the 1-month follow-up study was a sufficient indication for reintervention. Over the last 3 years of the study, type II endoleaks were treated only if the aneurysm size increased on follow-up CT scans.

All statistical analyses were performed by using Stata version 9.0 (StataCorp, College Station, Tex). Clinical features of patients with late failure were compared with those of the study cohort. Patients treated for a type II endoleak were compared with patients who had an untreated type II endoleak. Measured values are reported as percentages or means ± SD. The Student *t* test was used to compare the means of continuous variables, and the Pearson χ^2 test and Fisher exact test were used to compare categorical variables. $P \leq .05$ was considered statistically significant. Overall survival, freedom from late graft failure, and freedom from aneurysm-related mortality were calculated by using life-table analysis. The log-rank test was used to compare the Kaplan-Meier estimate of freedom from intervention for late failure.

RESULTS

The demographic features of the study cohort are displayed in Table I. The mean age in this cohort was 75.9 ± 7.4 years (range, 56.4-95.3 years), with 300 (92.3%) men and 25 (7.7%) women. The mean follow-up time was 836.4 ± 580.2 days (range, 30-2547 days). Cumulative follow-up rates were 37.2% (121 patients) at 3 years, 21.8% (71 patients) at 4 years, and 10.2% (33 patients) at 5 years. Overall, women were older than men at the time of operation (77.6 years compared with 75.7 years), but this was not statistically significant ($P = .23$). A total of 92 (28.3%) of the 325 patients were dead at the time of this study, and 25 patients (7.7%) were lost to follow-up.

Table I. Patient demographics of the cohort treated with the Zenith stent graft

Variable	*Data*
Age at operation (y)	
Mean ± SD	75.9 ± 7.4
Range	56.4-95.3
Sex	
Male	300 (92.3%)
Female	25 (7.7%)
Preoperative Creatinine (mg/dL)	
Mean ± SD	1.2 ± 0.5
Range	0.6-7.1
Follow-up (d)	
Mean ± SD	836.4 ± 580.2
Range	30-2547
Aneurysm size (mm)	
Mean ± SD	59.5 ± 9.4
Range	32-100
Medical comorbidities	
Diabetes mellitus	51 (17.0%)
Smoker	49 (16.0%)
Past smoker	210 (64.6%)
Cardiac disease	213 (66.4%)
COPD	102 (31.8%)

COPD, Chronic obstructive pulmonary disease.

There were a total of 9 (2.8%) instances of late failure, comprising limb occlusion (n = 2), aneurysm rupture (n = 1), type III endoleak (n = 3), limb kink without occlusion (n = 1), occlusion of a renal artery (n = 1), and graft infection (n = 1). The average time after stent-graft placement to late failure was 516.7 days (range, 40-1454 days). Three deaths were attributed to late failure: one each of aneurysm rupture, stent-graft infection, and infection of a femoral-femoral bypass graft placed after limb occlusion.

Table II shows the clinical characteristics of patients who experienced late failure compared with the study cohort. The preoperative creatinine level, medical comorbidities, aneurysm size, and length of follow-up were all similar between the two groups. Those who experienced late failure were older at the time of AAA repair than those who did not (79.9 vs 75.8 years), but this did not reach statistical significance ($P = .11$). There was also a disproportionately higher number of women who required reintervention, but this also did not reach statistical significance ($P = .15$).

The unadjusted Kaplan-Meier estimates for freedom from late failure are shown in Fig 1. Fig 1, *a*, shows the overall freedom from late failure in the entire cohort. Women seem to have increased rates of late failure over

Table II. Patient characteristics of those requiring intervention for late failure compared with the study cohort

Description	*Late failure (n = 9)*	*Study cohort (n = 316)*	P *value*
Age at operation (y)			.11
Mean ± SD	79.9 ± 5.3	75.8 ± 7.5	
Range	72.3-90.8	56.4-95.3	
Sex			.15
Male	7 (77.8%)	293 (92.7%)	
Female	2 (22.2%)	23 (7.3%)	
Creatinine (mg/dL)			.64
Mean ± SD	1.3 ± 0.5	1.2 ± 0.5	
Range	0.7-2.1	0.6-7.1	
Follow-up (d)			.73
Mean ± SD	903.7 ± 592.0	834.5 ± 580.7	
Range	174-1682	30-2547	
Aneurysm size (mm)			.97
Mean ± SD	59.3 ± 6.9	59.5 ± 9.4	
Range	43-67	32-100	
Medical comorbidities			
Diabetes mellitus	2 (22.2%)	49 (16.8%)	.65
Cardiac disease	3 (33.3%)	210 (67.3%)	.07
COPD	3 (33.3%)	99 (31.7%)	1.0

COPD, Chronic obstructive pulmonary disease.

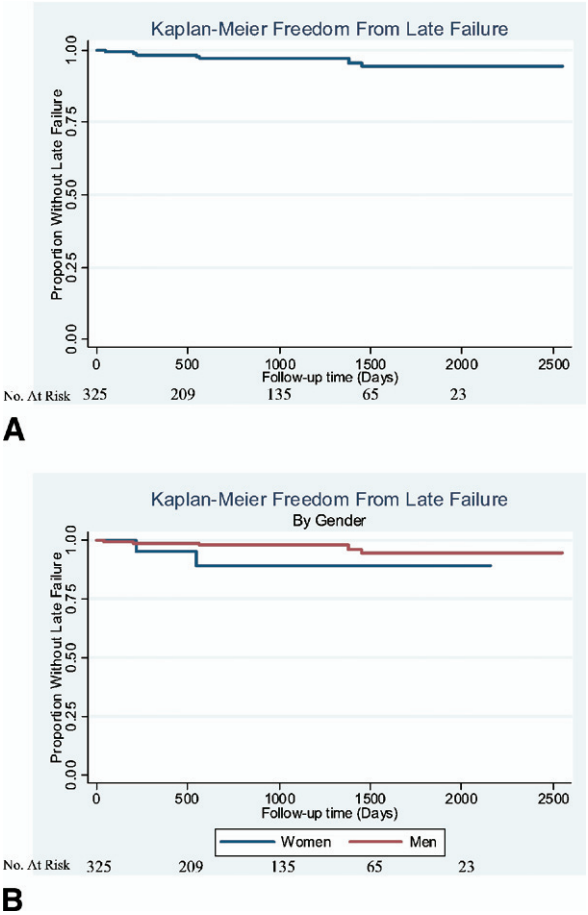


Fig 1. Kaplan-Meier estimate of freedom from late failure in (**A**) the entire cohort and in (**B**) women compared with men (P = .09). The number of patients at each interval is shown at the bottom of the graph.

time compared with men, as demonstrated in Fig 1, *b*. However, this association is not statistically significant (P = .09 by log-rank test). Fig 2, *a*, shows the Kaplan-Meier estimate of all-cause mortality, and Fig 2, *b*, shows overall freedom from aneurysm-related mortality.

There were 74 patients (23%) in our study cohort with a type II endoleak, of whom 19 underwent percutaneous intervention. The clinical characteristics of patients with treated and untreated type II endoleaks are shown in Table III. The 19 treated cases represent 5.8% of the entire study cohort. The overall intervention rate, including reintervention for late failure, is therefore 8.6% (28 patients).

DISCUSSION

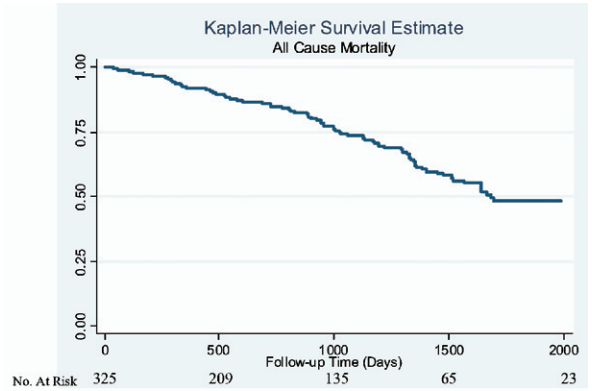
All the cases of failure and impending failure of endovascular AAA repair necessitated treatment. All limb occlusions resulted in bypass or thrombolysis, followed by stent insertion. All type III endoleaks resulted in the insertion of additional stent-graft components. The same is not true of type II endoleak, which was treated less aggressively as the study progressed.

No patient in this study developed a type I endoleak or underwent reintervention as a result of migration. The absence of clinically relevant proximal attachment failure probably reflects the effects of the barbed proximal stent of the Zenith stent graft. Other stent-graft designs, which lack barb-mediated proximal attachment, are subject to high rates of migration,[3] leading to secondary type I endoleak, reintervention, and aneurysm rupture.[8]

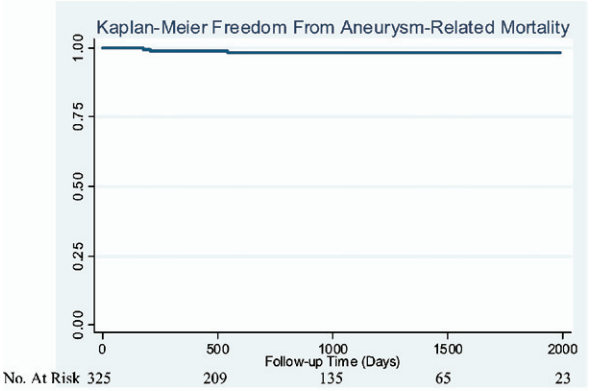
The type III endoleaks occurred on average 660 days after stent-graft insertion, thus indicating an unstable stent-graft structure or position. The implantation technique seems to have played a role. During the course of the study, we increased the degree of intercomponent overlap to a minimum of 1.5 stent body lengths, and none of the stent grafts implanted in the past 5 years has developed either component separation or type III endoleak.

Late graft occlusion occurred in 2 (0.6%) of 325 cases. Others studies have reported slightly higher rates,[1,2,6,9,10] and the Zenith stent graft has been noted to perform worse in this regard than other contemporary stent grafts. Our experience has shown that additional stent support, in the form of a Wallstent (Boston Scientific, Natick, Mass), is effective prophylaxis against graft occlusion, but at-risk cases can be difficult to identify.[11] Most of these Wallstents were inserted within a month of stent-graft implantation, if not at the initial operation. Only one patient underwent reintervention on the basis of the finding of impending graft limb occlusion (kinking) on routine follow-up imaging.

Large multicenter registries in Europe have shown high rates of late failure, due largely to a high incidence of stent fractures and graft erosion affecting one device,



A



B

Fig 2. Kaplan-Meier estimates of all-cause mortality (**A**) and aneurysm-related mortality (**B**). The number of patients at each interval is shown at the bottom of the graph.

the Stentor (later Vanguard) device (Boston Scientific, Natick, Mass).[1] No currently used stent grafts are so susceptible to structural degradation, but all are found to have fractures or small holes when explanted or studied with high-resolution imaging.[12] The Zenith device is no exception,[13] and we have seen stent fracture, barb separation, and top stent separation on routine plain abdominal radiographs. However, none has ever affected stent-graft function or led us to reintervene.

The unique feature of this study is the length of follow-up. The first cases in this series were performed in late 1998. The pivotal Zenith trial started in 2000, but only the 2-year data have as yet been published.[7] This article is based on more than 3 years of follow-up in 121 patients (and more than 5 years in 33 patients). We believe this to be a sound basis for assessing long-term results.

The findings reported in this study led us to change our routine follow-up protocol after endovascular AAA repair. We still obtain CT scans but omit intravenous contrast enhancement if the 1-month postoperative CT scan demonstrates appropriate position and function and lack of an endoleak. All type II endoleaks in our study cohort were detected on the 1-month postoperative CT scan. We believe that the potential nephrotoxicity[14] is not justified, given the infrequent diagnosis of treatable problems such as secondary endoleak (types I and III) and graft limb kinking. We still perform noncontrast CT scans and plain abdominal radiographs as routine follow-up to look for changes in aneurysm diameter or changes in stent-graft structure. The yield may be low, but neither test has any serious side effects.

Table III. Clinical features of patients treated for type II endoleak compared with those with untreated type II endoleak

Description	*Treated type II EL (n = 19)*	*Untreated type II EL (n = 55)*	P *value*
Age at operation (y)			.65
Mean ± SD	77.9 ± 6.2	77.1 ± 7.2	
Range	67.2-90.3	58.9-95.3	
Sex			.06
Male	14 (73.7%)	50 (90.9%)	
Female	5 (26.3%)	5 (9.1%)	
Creatinine (mg/dL)			.92
Mean ± SD	1.2 ± 0.4	1.3 ± 0.4	
Range	0.9-2.4	0.6-2.3	
Follow-up (d)			.07
Mean ± SD	1249.4 ± 532.2	976.1 ± 555.4	
Range	181-2156	34-2247	
Aneurysm size (mm)			.50
Mean ± SD	61.2 ± 12.5	59.6 ± 6.8	
Range	39-93	45-79	

EL, Endoleak.

AUTHOR CONTRIBUTIONS

Conception and design: JSH, LMR, DBS, JHR, TAMC
Analysis and interpretation: JSH, LMR, DBS, NS, JHR, TAMC
Data collection: JSH, LMR, DBS, NS, JHR, TAMC
Writing the article: JSH, TAMC
Critical revision of the article: JSH, LMR, DBS, NS, JHR, TAMC
Final approval of the article: JSH, LMR, TAMC
Statistical analysis: JSH
Obtained funding: JHR, TAMC
Overall responsibility: JSH

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DISCUSSION

Dr William Quinones-Baldrich (Los Angeles, Calif): This is a review of events occurring after 30 days of implantation of the Zenith aortic endograft for the treatment of infrarenal abdominal aortic aneurysms. The authors report an incidence of type II endoleak of 5.8%, which is quite low, and no type I endoleaks. Similarly, graft occlusions were rare, only one requiring surgical treatment with a femorofemoral bypass. The authors also find that hypertensive patients with type II endoleaks more often require intervention for increase in the size of the aneurysm. The latter is an important finding as it strongly suggests that in the presence of a type II endoleak, blood pressure control is of benefit.

The authors also conclude that routine follow-up imaging plays a limited role in the identification and prevention of graft failure. They now recommend CT scan without contrast, noting that the size of the aneurysm and detection of migration are the most important factors during follow-up. Several reports are noting a gradual decrease in renal function in patients treated with endovascular grafts regardless of whether or not suprarenal fixation is present. Therefore, avoiding contrast during follow-up in these patients is important.

The occurrence of type III endoleaks leads the authors to increase the degree of intercomponent overlap to a minimum of 1½ stents. Their experience with graft limb occlusion has led them to be more aggressive in placing stents in areas of concern at the time of implantation. These are excellent recommendations based on the authors' extensive experience with this device.

Unfortunately, this report only presents part of the picture. By omitting events during the first 30 days of follow-up, the incidence of postimplantation events is underestimated. In the manuscript, it is clear that several type I endoleaks were treated with proximal extensions, some limb occlusions were treated with thrombolysis and stent placement, and some type III endoleaks were also detected. They have also observed stent fractures, barb separation, and top stent separation. The latter events are more likely to have occurred after 30 days. I have several questions for the authors.

During follow-up you found that women tend to have more events than men. My first question is why are there so few women in your cohort? Does gender influence your recommendations? Even though it is not the emphasis of your presentation today, could you give us information on events occurring in the first 30 days? What is the overall incidence of type I, II, and III endoleaks in your experience? When and how often were the stent fractures, bar and/or stent separation observed? Do you have information on long-term renal function in patients receiving the Zenith endograft for treatment of their abdominal aortic aneurysms? And finally, in my practice I usually obtain a CT scan as baseline at a month, and if everything looks well, I will then alternate duplex scan and CT during the follow-up. Have you had any experience using duplex scan for follow-up?

I congratulate the authors on an excellent experience and thank you for providing me a copy of the manuscript in advance of the meeting. I also wish to thank the society for the privilege of discussing this paper.

Dr Jade Hiramoto: Thank you, Dr Quinones. With regard to your first question, we did not alter our recommendations for treatment based on gender. We did have very few women in our study. Part of this may be explained by the fact that a large proportion of our operations were performed at the VA, where essentially all of the patients are men. Gender may initially have played a role in our recommendations when we were worried that because of access issues they might not be appropriate candidates; however, we use the same anatomic criteria for all patients. We do not take gender into consideration now. We look at the diameters of our access vessels and make appropriate recommendations based on those size measurements.

Women did tend to do worse in terms of late graft failure. They were also more likely to require treatment for their type II endoleaks, and if you actually look at all interventions—early complications, late complications, treatment of type II endoleaks—it is statistically significant. It did not reach statistical significance when you just looked at each of these separately, but if you pooled all interventions they (women) did worse. I think it is difficult to explain. The women tended to be older on presentation for their aneurysm repair, but there did not appear to be an interaction between age and gender. Gender itself was an independent predictor.

Again, this talk was really devoted towards looking at the long-term complications since this device has been in use since 1998 at UCSF, and we wanted to analyze and present our long-term data. However, with regards to complications from within the first 30 days, there were a total of 10, for an overall late and early complication rate of 19 in the entire cohort. The majority of the early complications, as you might imagine, were limb thromboses. It was probably 7 out of those 10. There were probably 1 or 2 type I endoleaks and no treated type II endoleaks in the first 30 days.

With regards to stent fracture, barb fractures, and stent separation, there has been a total of four in our series and they have not required treatment. They have been recognized on the follow-up abdominal x-rays and followed but not treated.

In terms of the long-term renal function of these patients, I do not have all of their data analyzed at this point to determine the number of patients who have had worsening renal function or

those who have required dialysis, but we can certainly look back at our data. I do have their preoperative values, and there was quite a range, but the average preoperative creatinine was 1.2. With regards to duplex ultrasound, I think that it is an excellent imaging modality. I think in the face of going to noncontrast CT scans if the 1-month postoperative contrast-enhanced CT does not demonstrate enlargement of the aneurysm or an endoleak, I think a duplex would be a great adjunctive measure to include. This would be especially useful in a patient who maybe has some renal insufficiency, gets a noncontrast CT scan, and there is a question of aneurysm sac enlargement; perhaps a duplex would be useful in that patient to determine if they have evidence of an endoleak.

8. "Late Complications After Endovascular Aneurysm Repair Using the Zenith Stent Graft." Discussion by Benjamin Starnes, Tacoma, WA.

Dr Benjamin Starnes (Tacoma, Wash): I congratulate you on a very impressive experience. One of the unique aspects, and in my opinion, one of the favorable aspects of the Zenith system is that the main body is sized all the way down to the aortic bifurcation and this theoretically assists in preventing distal migration. You had one case where the renal artery was occluded, you presumed, because of overlap of the orifice of the renal artery. I am wondering, because I have had one similar case, have you ever seen any instance of proximal migration of the graft after aneurysm remodeling, especially in very large aortic aneurysms?

Dr Hiramoto: Not to my knowledge, and certainly not in this series of patients. This one case of renal artery occlusion that we presented today was clearly an intraoperative event that was not recognized at the time of the procedure. Looking back at the intraoperative angiogram, you see that the top of the covered portion of the stent graft was almost completely covering that renal artery. This was the only patient in which that occurred, and again, I think this was an early mistake that was recognized late. This was not a case of proximal migration, nor have we observed proximal migration in this series of patients.

INVITED COMMENTARY

Mark F. Fillinger, MD, *Lebanon, NH*

I enjoyed reading this article, which is important because of its size and length of follow-up (at least 3 years in 121 of 325 patients). The clinical results are excellent, with a low rate of reintervention and aneurysm-related death beyond 30 days. That being said, the follow-up is primarily from 30 days to 5 years, defined as "mid-term" by Society for Vascular Surgery reporting standards,[1] and should be taken in that context.

I was initially taken aback when I read that "Large prospective studies and registries have failed to produce the kind of device specific data. . .needed for informed decisions on patient selection, device selection, and follow-up." I suspect the authors of the DREAM, EVAR, EUROSTAR, and other studies would take issue with that comment.[2-5] Nonetheless, I think Hiramoto et al are pointing out that a large single-center study can bring a unique perspective when it combines consistency in evaluation and follow-up with access to the patient's chart and raw imaging data. Of course, this unique perspective can lead to bias, but it can also provide unique insights.

Most of the insights in this paper have a sound basis in fact, as well as some controversy: (1) The Zenith device has very good mid-term results, consistent with EUROSTAR, clinical trials, and other studies. I will avoid discussing the "barbs" regarding other devices, as this is not a concurrent comparative study including other devices. (2) Opinions regarding intervention for type II endoleak are changing. I would like to have seen more information about how often the treatment of endoleak was successful in stopping the endoleak or resolving aneurysm enlargement, as this would have helped influence decision-making regarding follow-up and intervention. (3) When a device has a low rate of failures and reinterventions, any imaging modality will have a low yield. Even at an intervention rate of 8.5% over an average 2.3 years' follow-up, however, postoperative imaging should clearly be performed. The authors make a good point that if there is no endoleak on initial computed tomography, if there is no migration of components, and if the aneurysm is shrinking, no contrast should be needed on future computed tomography for a device with this track record. Noncontrast computed tomography provides good information about migration, deformation, aneurysm sac size, and, in some cases, fracture (the only missing parameter is endoleak). This article should not be used as an excuse to avoid imaging studies, nor do the authors suggest that.

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